

CLAIMS

1. A test strip for measuring glucose in a blood sample, said test strip comprising:
 - a first insulating sheet, said first insulating sheet having a proximal end and a distal end, said proximal end being narrower than said distal end;
 - 5 at least four electrodes disposed on said first insulating sheet, said at least four electrodes including a working electrode, a counter electrode, a fill-detect anode, and a fill-detect cathode;
 - a plurality of electrical contacts disposed on said first insulating sheet, said plurality of electrical contacts including a working electrode contact, a counter electrode contact, a fill-detect anode contact, and a fill-detect cathode contact;
- 10 a plurality of conductive traces disposed on said first insulating sheet, said plurality of conductive traces electrically connecting said working electrode to said working electrode contact, said counter electrode to said counter electrode contact, said fill-detect anode to said fill-detect anode contact, said fill-detect cathode to said fill-detect cathode contact;
- an auto-on conductor disposed on said first insulating sheet;
- 15 a first dielectric layer disposed on said first insulating sheet, said first dielectric layer covering portions of said working electrode and said counter electrode, so as to define an exposed working electrode portion and an exposed counter electrode portion;
- a second dielectric layer disposed on said first dielectric layer, said second dielectric having a slot, said working electrode, said counter electrode, said fill-detect anode, and said fill-
 - 20 detect cathode being disposed in said slot, said slot having a proximal end and a distal end, said proximal end of said slot being aligned with said proximal end of said first insulating sheet;

a reagent layer disposed in said slot, said reagent layer including glucose oxidase and a mediator;

an adhesive layer disposed on said second dielectric layer, said adhesive layer having a break extending from said slot to a vent opening; and

5 a second insulating sheet disposed on said adhesive layer, said second insulating sheet covering said slot and at least a portion of said break, said second insulating sheet having a proximal end and a distal end, said proximal end of said second insulating sheet being aligned with said proximal end of said slot,

wherein said slot defines a sample chamber in said test strip, said slot being dimensioned
10 to draw said blood sample in through said proximal end of said slot by capillary action.

2. The test strip of claim 1, wherein said counter electrode includes a first section and a second section, said working electrode being disposed on said first insulating sheet between said first second and said second section.

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3. The test strip of claim 1, wherein said at least four electrodes are formed by a first conductive ink printed on said first insulating sheet.

4. The test strip of claim 3, wherein said first conductive ink contains graphite.

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5. The test strip of claim 4, wherein said electrical contacts, said conductive traces, and said auto-on conductor are formed by a second conductive ink printed on said first insulating sheet.

5 6. The test strip of claim 5, wherein said second conductive ink contains silver.

7. The test strip of claim 1, wherein said test strip has a thick section and a thin section, said thick section including said proximal end, said thin section including said distal end, said electrical contacts and said auto-on conductor being located in said thin section.

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8. The test strip of claim 1, wherein said reagent layer covers said exposed working electrode portion.

9. The test strip of claim 1, wherein said second insulating sheet is transparent.

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10. A test strip for testing a blood sample, said test strip comprising:

a sample chamber for said blood sample;

at least four electrodes for measuring at least one electrical characteristic of said blood sample in said sample chamber, said at least four electrodes including a working electrode, a counter electrode, a fill-detect anode, and a fill-detect cathode;

20 a plurality of electrical contacts electrically connected to said at least four electrodes; and

at least one auto-on electrical contact electrically isolated from said at least four electrodes.

11. The test strip of claim 10, further comprising:
5 a reagent layer disposed in said sample chamber.

12. The test strip of claim 10, wherein said sample chamber has a first opening for receiving said blood sample and a second opening for venting said sample chamber.

10 13. The test strip of claim 12, wherein said sample chamber is dimensioned to draw said blood sample in through said first opening by capillary action.

14. The test strip of claim 12, wherein said test strip has a proximal end and a distal end, said first opening being located at said proximal end.

15 15. The test strip of claim 14, wherein said proximal end is narrower than said distal end.

20 16. The test strip of claim 14, wherein said test strip has a thick section and a thin section, said thin section including said proximal end.

17. The test strip of claim 16, wherein said plurality of electrical contacts and said at least one auto-on electrical contact are located in said thin section.

18. A method of making a plurality of test strips, said method comprising:
5 forming a plurality of test strip structures on a first insulating sheet, wherein each test strip structure is formed by:

(a) forming a first conductive pattern on said first insulating sheet, said first conductive pattern including at least four electrodes, said at least four electrodes including a working electrode, a counter electrode, a fill-detect anode, and a fill-detect cathode;

10 (b) forming a second conductive pattern on said first insulating sheet, said second conductive pattern including a plurality of electrode contacts for said at least four electrodes, a plurality of conductive traces electrically connecting said at least four electrodes to said plurality of electrode contacts, and an auto-on conductor;

15 (c) applying a first dielectric layer over portions of said working electrode and said counter electrode, so as to define an exposed working electrode portion and an exposed counter electrode portion;

(d) applying a second dielectric layer to said first dielectric layer, said second dielectric layer defining a slot, said working electrode, said counter electrode, said fill-detect anode, and said fill-detect cathode being disposed in said slot;

20 (e) forming a reagent layer in said slot, said reagent layer including glucose oxidase and a mediator;

(f) forming an adhesive layer on said second dielectric layer, said adhesive layer having a break extending from said slot; and

(g) attaching a second insulating layer to said adhesive layer, such that said second insulating sheet covers said slot but not said electrode contacts or said auto-on conductor;

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separating said plurality of test strip structures into said plurality of test strips, each of said test strips having a proximal end and a distal end, with said slot extending to said proximal end, said proximal end being narrower than said distal end.

10 19. The method of claim 18, wherein forming a first conductive pattern on said first insulating sheet comprises:

printing a first conductive ink on said first insulating sheet, said first conductive ink containing graphite.

15 20. The method of claim 19, wherein forming a second conductive pattern on said second insulating sheet comprises:

printing a second conductive ink on said second insulating sheet, said second conductive ink containing silver.

21. A method of making a plurality of test strips, said method comprising:
forming a plurality of test strip structures on one sheet, each of said test strip structures
including:

- (a) a sample chamber;
- 5 (b) a plurality of electrodes, including a working electrode, a counter electrode, a fill-detect anode, and a fill-detect cathode;
- (c) a plurality of electrical contacts electrically connected to said plurality of electrodes; and
- (d) at least one auto-on electrical contact, electrically isolated from said plurality of electrodes; and

10 separating said test strip structures into said plurality of test strips.

22. The method of claim 21, wherein each of said test strip structures includes a reagent layer disposed in said sample chamber.

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23. The method of claim 21, wherein separating said test strip structures into said plurality of test strips comprises:

punching said plurality of test strip structures to form a plurality of tapered test strip structures, each of said tapered test strip structures having a tapered section.

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24. The method of claim 23, wherein separating said test strip structures into said plurality of test strips further comprises:

slitting said plurality of tapered test strip structures into said plurality of test strips.

5 25. A method of measuring glucose in a blood sample, said method comprising:
providing a test strip, said test strip having a sample chamber, with a working electrode, a counter electrode, a pair of fill-detect electrodes, and a reagent layer disposed in said sample chamber, said reagent layer including glucose oxidase and a mediator, said test strip including an auto-on conductor;

10 inserting said test strip into a meter, said meter being in a sleep mode;
said meter detecting an auto-on current through said auto-on conductor and responsively entering an active mode;

 said meter validating said working and counter electrodes by applying a first validation voltage between said working and counter electrodes;

15 said meter validating said fill-detect electrodes by applying a second validation voltage between said fill-detect electrodes, while said first validation voltage is applied between said working and counter electrodes;

 applying said blood sample to said sample chamber;
said meter detecting said blood sample at a first location in said sample chamber by
20 applying a drop-detect voltage between said working and counter electrodes and measuring a drop-detect current flowing between said working and counter electrodes;

said meter detecting said blood sample at a second location in said sample chamber by applying a fill-detect voltage between said fill-detect electrodes and measuring a fill-detect current flowing between said fill-detect electrodes;

5 after waiting an incubation time period, said meter applying an assay voltage between said working and counter electrodes and making at least one measurement of the resulting current through said working electrode; and

said meter determining a measured glucose level from said at least one current measurement.

10 26. The method of claim 25, further comprising:

said auto-on current developing an auto-on voltage drop across said auto-on conductor; and

said meter measuring said auto-on voltage drop.

15 27. The method of claim 25, further comprising:

said meter measuring any leakage current through said working electrode, while applying said first validation voltage between said working and counter electrodes; and

if said leakage current exceeds a first predetermined level, said meter indicating an error condition.

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28. The method of claim 25, further comprising:

said meter measuring any leakage current through one of said fill-detect electrodes, while applying said first validation voltage between said working and counter electrodes and said second validation voltage between said fill-detect electrodes; and

5 if said leakage current exceeds a second predetermined level, said meter indicating an error condition.

29. The method of claim 25, further comprising:

if said drop-detect current does not reach a drop-detect threshold value within a 10 predetermined time period, said meter indicating an error condition.

30. The method of claim 25, further comprising:

if said drop-detect current reaches a drop-detect threshold value within a predetermined time period, said meter:

15 a) switching said working and counter electrodes to a high impedance state relative to said fill-detect electrodes;

b) starting a fill time period; and

c) starting said incubation time period.

20 31. The method of claim 30, further comprising:

if said fill-detect current does not reach a fill-detect threshold value within said fill time period, said meter indicating an error condition.

32. The method of claim 30, further comprising:

if said fill-detect current reaches a fill-detect threshold value within said fill time period,
said meter providing a user-discriminable indication.

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33. A method of using a test strip to test a blood sample, said test strip including a sample chamber, a working electrode, a counter electrode, a pair of fill-detect electrodes, and an auto-on conductor, said method comprising:

inserting said test strip into a meter, said meter being in a sleep mode;

10 said meter detecting an auto-on current through said auto-on conductor and responsively entering an active mode;

applying said blood sample to said sample chamber;

said meter detecting said blood sample in said sample chamber by applying a fill-detect voltage between said fill-detect electrodes and measuring a fill-detect current flowing between
15 said fill-detect electrodes;

said meter applying an assay voltage between said working and counter electrodes and making at least one measurement of the resulting current; and

said meter determining a test result from said at least one current measurement.

20 34. The method of claim 33, further comprising:

said auto-on current developing an auto-on voltage drop across said auto-on conductor;
and

said meter measuring said auto-on voltage drop.

35. The method of claim 33, further comprising:

if said fill-detect current reaches a fill-detect threshold value within a predetermined time
5 period, said meter providing a user-discriminable indication.

36. The method of claim 33, further comprising:

said meter detecting said blood sample in said sample chamber by applying a drop-detect
voltage between said working and counter electrodes and measuring a drop-detect current
10 flowing between said working and counter electrodes.

37. The method of claim 36, further comprising:

if said drop-detect current reaches a drop-detect threshold value within a predetermined
time period, said meter starting an incubation time period.

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38. The method of claim 37, wherein said meter applies said assay voltage after said
incubation time period.

39. A method of strip identification, said method comprising:

inserting a strip into a meter, said strip including an auto-on conductor, said meter being
in a sleep mode;

5 said meter detecting said strip, by detecting a current flow through said auto-on
conductor, and responsively entering an active mode;

 said meter measuring a voltage drop across said auto-on conductor;

 said meter identifying said strip as either a test strip or a check strip based on said voltage
drop;

 if said strip is a test strip, said meter performing a test strip sequence; and

10 if said strip is a check strip, said meter performing a check strip sequence.

40. The method of claim 39, wherein said meter identifies said strip as a test strip if
said voltage drop is below a predetermined value.

15 41. The method of claim 40 wherein said meter identifies said strip as a quality
control strip if said voltage drop is above said predetermined value.

42. A removable data storage device for a meter, said meter measuring using test
strips to measure glucose levels in blood samples, said removable data storage device
20 comprising:

 a carrier having a proximal end and a distal end, said carrier being keyed for inserting
said distal end into said meter in a preferred orientation;

a circuit board mounted to said carrier, said circuit board including a plurality of electrical contacts for electrically connecting to said meter, said plurality of electrical contacts including a ground contact and a voltage supply contact, said ground contact extending closer to said distal end than said voltage supply contact; and

5 a memory mounted to said circuit board and electrically connected to said plurality of electrical contacts, said memory storing data for use by said meter, said data including at least one calibration parameter for use with at least one test strip,

whereby when said removable data storage device is inserted into said meter in said preferred orientation, said ground contact becomes electrically connected to said meter before
10 said voltage supply contact.

43. The removable data storage device of claim 42, wherein said at least one calibration parameter corrects for temperature.

15 44. The removable data storage device of claim 42, wherein said data identifies a brand of said at least one test strip.

45. The removable data storage device of claim 42, wherein said data identifies a model of said meter.

20 46. The removable data storage device of claim 42, wherein said data identifies an expiration date of said at least one test strip.

47. The removable data storage device of claim 42, wherein said data specifies at least one time period duration to be used by said meter.

5 48. The removable data storage device of claim 42, wherein said data specifies at least one voltage to be used by said meter.

49. The removable data storage device of claim 42, wherein said data specifies a number of current measurements to be taken by said meter.

10 50. The removable data storage device of claim 49, wherein said data specifies an averaging method of said current measurements.

51. A meter for use in combination with a test strip for measuring a glucose level in a blood sample applied to a sample chamber in said test strip, said test strip having at least four electrodes disposed in said sample chamber, said at least four electrodes including a working electrode, a counter electrode, and a pair of fill-detect electrodes, said test strip having a thin section and a thick section, said thin section including a plurality of test strip contacts for said at least four electrodes and an auto-on conductor, said meter comprising:

20 a first connector for receiving said test strip, said first connector including meter contacts for electrically connecting to said test strip contacts and said auto-on conductor, said first connector being sized to receive said thin section but not said thick section of said test strip;

a second connector for receiving a removable data storage device, said removable data storage device storing data for use by said meter;

a processor;

a memory;

5 a display;

a plurality of machine language instructions stored in said memory and executable by said processor for:

- a) saving said data from said removable data storage device into said memory;
- b) performing a test strip sequence when said test strip is inserted in said first connector to obtain at least one current measurement related to said glucose level;
- c) determining a glucose level in said blood sample from said at least one current measurement and said data stored in said memory; and
- d) displaying said glucose level on said display;

a first electrode circuit for applying at least a first voltage, selected by said processor, between said working and counter electrodes when said test strip is inserted in said first connector, said first electrode circuit including a first digital-to-analog converter;

a second electrode circuit for applying at least a second voltage, selected by said processor, between said fill-detect electrodes when said test strip is inserted in said first connector, said second electrode circuit including a second digital-to-analog converter;

20 an auto-on circuit for developing an auto-on current through said auto-on conductor when said test strip is inserted in said first connector and for bringing said meter from a sleep mode to an active mode in response to said auto-on current; and

at least one analog-to-digital converter for measuring currents flowing between said working and counter electrodes and flowing between said fill-detect electrodes and for measuring an auto-on voltage drop across said auto-on conductor resulting from said auto-on current.

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52. The meter of claim 51, wherein said test strip sequence comprises:

validating said working and counter electrodes by applying a first validation voltage between said working and counter electrodes;

validating said fill-detect electrodes by applying a second validation voltage between said 10 fill-detect electrodes, while said first validation voltage is applied between said working and counter electrodes;

detecting said blood sample at a first location in said sample chamber by applying a drop-detect voltage between said working and counter electrodes and measuring a drop-detect current flowing between said working and counter electrodes;

15 detecting said blood sample at a second location in said sample chamber by applying a fill-detect voltage between said fill-detect electrodes and measuring a fill-detect current flowing between said fill-detect electrodes; and

after waiting an incubation time period, applying an assay voltage between said working and counter electrodes and making at least one measurement of the resulting current flowing 20 between said working and counter electrodes.

53. A meter for use in combination with a test strip, said test strip including a working electrode, a counter electrode, a pair of fill-detect electrodes, and an auto-on conductor, said meter comprising:

a strip connector for receiving said test strip;

5 a processor;

a memory;

a plurality of machine instructions stored in said memory and executable by said processor for performing a test strip sequence;

10 a data acquisition system, controlled by said processor, for applying at least a first voltage between said working and counter electrodes and measuring any resulting current flowing between said working and counter electrodes, for applying at least a second voltage between said fill-detect electrodes and measuring any resulting current flowing between said fill-detect electrodes, and for measuring a voltage drop across auto-on conductor, when said test strip is inserted in said strip connector, said data acquisition system including at least one digital-to-analog converter and at least one analog-to-digital converter.

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20 54. The meter of claim 53, wherein said data acquisition system includes a wake-up circuit, said wake-up circuit detecting said auto-on conductor when said test strip is inserted in said strip connector and responsively bringing said data acquisition system from a sleep mode into an active mode.

55. The meter of claim 53, wherein said test strip sequences comprises:
applying an assay voltage between said working and counter electrodes and making at least one measurement of the resulting current flowing between said working and counter electrodes.

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56. The meter of claim 55, wherein said test strip sequence further comprises:
detecting said blood sample in said sample chamber by applying a fill-detect voltage between said fill-detect electrodes and measuring a fill-detect current flowing between said fill-detect electrodes.

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57. The meter of claim 56, wherein said test strip sequence further comprises:
detecting said blood sample at a first location in said sample chamber by applying a drop-detect voltage between said working and counter electrodes and measuring a drop-detect current flowing between said working and counter electrodes.